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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,709	STROMBERG ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-14 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-14 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted on 8/19/04 is made. Claims 1-7, 9-14 and 20-24 are currently pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7, 9-14 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the claim fails to adequately describe the structure of the composition which is claimed. The claim recites four residues of any oligopeptide which has dental caries protective properties. It is unclear what the other, 6, 5, etc. amino acids may consist of and accordingly the current claims fail to particularly point out an distinctly claim the subject matter without ambiguity. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of the function, having dental caries protective properties, does not adequately define the claimed protein. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification

will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claims 2-4 are improperly dependent because claim 1 recites that the oligopeptide comprises 'ProArgGlyArg' yet SEQ ID NOs:1-6 which are recited in the dependent claims and these sequences do not contain 'ProArgGlyArg'. Accordingly, claims 2-4 which recite that the oligopeptide may be any one of SEQ ID NOs:1-6 do not properly depend from claim 1 because claim 1 requires the oligopeptide to have 'ProArgGlyArg'. Only SEQ ID Nos: 7-13 contain the sequence 'ProArgGlyArg'. Correction is required.

Claim 20 is vague and indefinite because it recites wherein the oligopeptide of claim 1 (which comprising ProArgGlyArg) comprises at least one ProGly sequence. However, claim 1 allows for pentapeptides; therefore, it is unclear how a pentapeptide could consist of 6 amino acids. Additionally, the claim is vague and indefinite because it is unclear in what position the 'ProGly' sequence would occur.

Claim Rejections - 35 USC § 112-Written Description

4. Claim 1, 5, 6 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an oligopeptide consisting of an amino acid sequence selected from the group consisting of: SEQ ID NOs: 1-13 and therefore the written description is not commensurate in scope with a claim drawn to any

pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide which comprises ProArgGlyArg and has dental caries protective properties.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of the encompassed oligopeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The oligopeptide itself is required.

Therefore only an oligopeptide consisting of an amino acid sequence selected from the group consisting of: SEQ ID NOs: 1-13, but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

Response to Applicants' Arguments:

Applicants argue that specifying that the oligopeptide (pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide) comprises ProArgGlyArg renders moot the rejection. This has been fully and carefully considered

but is not deemed persuasive. The specification only teaches that SEQ ID Nos: 1-13 have dental caries protective properties. No other oligopeptides are recited in the instant specification. The specification does not teach what the other six, five, four, etc. amino acids may be. conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The oligopeptide itself is required.

Claim Rejections - 35 USC § 112-Scope of Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1, 5, 6 and 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific oligopeptides recited in dependent claims, does not reasonably provide enablement for any pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide which comprises ProArgGlyArg. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches specific peptides which are acidic peptides derived from PRP-1. The specification teaches that these specific peptides possess qualities that would be effective in treating dental caries. The instant claims allows for the inclusion of any amino acids as long as the ProArgGlyArg present, i.e. 6 of the

decapeptide residues could be tryptophan or any of the other known amino acids. The specification is not enabled for the scope of this invention. It is also unpredictable if any of these other oligopeptides would possess properties effective in preventing or treating dental caries. One could expect changes in the amino acid make-up of the oligopeptide to cause varying degrees of loss of protection and function. The claims should be limited to the specific peptides generated by Applicants. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

Response to Applicants' Arguments:

Applicants argue that specifying that the oligopeptide (pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide) comprises ProArgGlyArg renders moot the rejection. This has been fully and carefully considered but is not deemed persuasive. The specification only teaches that SEQ ID Nos: 1-13 have dental caries protective properties. No other oligopeptides are recited in the

instant specification. The specification does not teach what the other six, five, four, etc. amino acids may be. One could expect changes in the amino acid make-up of the oligopeptide to cause varying degrees of loss of protection and function. The additional amino acids could completely change the acidity of the peptide thereby nullifying its ability to treat or prevent dental caries.

Claim Rejections - 35 USC § 112-New Matter

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5, 6 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new limitation "wherein the oligopeptide comprises the sequence ProArgGlyArg" in claim 1 appears to be new matter. The original specification and claims fail to identify the sequence 'ProArgGlyArg'. The sequence 'ArgGlyArgProGln" is recited on page 8 of the specification and original claim 2; however, the peptide 'ProArgGlyArg' was not individually identified or singled out. The singling out of this subsequence, not before noted in the disclosure, does not meet the written description requirement.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claim 1 is are rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi et al (J.Immunol. 1994, 152(7): 3645-3653).

Yamauchi et al teach the oligopeptides 'AAP**PRGR**' and 'AP**PRGR**' (heptapeptide and hexapeptide). The phrase "having dental caries protective properties' is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the structure of Yamauchi is identical to that recited in claim 1 it would inherently possess dental caries protective properties'.

11. Claims 1 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al (US 6,084,066).

Evans et al teaches the oligopeptides '**ProArgGlyArg**GlyMetProGlnPro' (nonapeptide). See SEQ ID NO: 113 in the sequence listing. Evans teaches the administration of the peptide with a carrier. See columns 4-5 for acceptable carriers and bottom of column 20 for administration guidelines. The phrase "having dental caries protective properties' is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the structure taught by Evans et al is identical to that recited in claim 1 it would inherently possess dental caries protective properties'.

Status of Claims:

12. No claims are allowed. Numerous oligopeptides comprising the sequence 'ProArgGlyArg' (pentapeptides, hexapeptides, heptapeptides, octapeptides, nonapeptides or decapeptides) were found in the prior art. This feature is not novel.

'An oligopeptide having dental caries protective properties **consisting of** an amino acid sequence selected from SEQ ID Nos: 1-13' is free of the prior art. Methods of treating and protecting against dental caries using said oligopeptides would also be allowed. Applicants should limit the scope of their claims to the specific oligopeptides, i.e., SEQ ID Nos:1-13.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 10/28/04

Jennifer Graser
Primary Examiner
Art Unit 1645